

### ***Remarks***

Reconsideration of this Application is respectfully requested.

Claims 287-432, 434-442, 446- 493, 495-503, 506-521, 523-531, 535-539, 541-549, 553-608, 611-619 and 622 are pending in the application, with claims 287, 300, 319, 340, 351, 362, 374, 389, 404, 416, 431, 446, 459, 476, 492, 507, 518, 535, 553, 565, 580, 595 and 608 being the independent claims. As of May 21, 2003, the mailing date of Paper No. 41, the status of the claims is as follows: claims 300-318, 340-350, 374-388, 416-430, 459-475 and 595-607 are allowed; claims 287-299, 319, 326-339, 351, 353-373, 389, 391-415, 431, 434-442, 446-458, 476, 478-493, 495-503, 506-521, 523-531, 535-539, 541-549, 553-565, 567-594, 608, 611-619, and 622 stand rejected; claims 320-325, 352, 390, 432, 477, and 566 stand objected to; and claims 1-286, 433, 443-445, 494, 504-505, 522, 532-534, 540, 550-552, 609, 610, and 620-621 were previously canceled.

Based on the attached exhibits and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

### ***Rejections under 35 U.S.C. §102***

The Examiner has rejected pending claims 492, 493, 495, 507, 508, 518-521, 523, 535-539, 541, 608 and 611 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,072,047 ("the '047 patent"), in view of the sequence presented in FIG. 1 therein.

The Examiner asserts that this sequence receives priority back to March 12, 1997 (Paper No. 34, pages 2 and 5).

In the Amendment and Reply dated February 21, 2003, Applicants argued that the Examiner could not rely on the March 12, 1997 priority date in order to make a rejection under 102(e), because that priority application does not support the issued claims of the '047 patent under 35 U.S.C. § 112. *In re Wertheim*, 646 F.2d 527 (CCPA, 1981). The Examiner argued that *Wertheim* is not applicable, citing MPEP 2136.03 IV. *See* Paper No. 41 at p. 2.

Applicants respectfully traverse. Applicants maintain that *Wertheim* is fully applicable in this situation. The doctrine set out by the Court of Customs and Patent Appeals in *Wertheim* clearly states that a U.S. patent only qualifies as prior art under 35 U.S.C. § 102(e) as of *the effective filing date of that patent's claims*. None of the issued claims in the '047 patent can claim priority back to March 12, 1997. Therefore, the '047 patent cannot properly be cited as prior art against the present application.

While Applicants maintain that the rejection under 35 U.S.C. § 102(e) should be withdrawn under *Wertheim*, Applicants further assert that prior to March 12, 1997, they were in possession, in the United States, of at least the sequences relevant to the subject matter of the pending claims, and had further established that the protein encoded by the cDNA comprising these sequences was a Tumor Necrosis Factor (TNF) receptor family member containing a death domain. In support of this assertion, Applicants submit herewith a Declaration under 37 C.F.R. § 1.131 ("the 131 declaration") by inventors Jian Ni, Reiner L. Gentz, Guo-Liang Yu, and Craig A. Rosen, with attached Exhibits A, B, and C.<sup>1</sup>

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<sup>1</sup> "Exhibit A" of the 131 declaration submitted herewith is the same as the Exhibit A of a prior Declaration under 37 C.F.R. § 1.131, which was submitted in Applicants' Amendment and Reply filed on June 4, 2002. In Paper No. 34, the Examiner alleged that the sequence disclosed in Exhibit A of the prior declaration was insufficient, because it allegedly showed only nucleotides 1080-1200 of SEQ ID NO:1, where Figure 1 of the '047 patent disclosed a sequence equivalent to 1048-1200 of SEQ ID NO:1. Applicants note that nucleotides corresponding to 1048 to 1079 of SEQ ID NO:1 are on the first page of the 2-page Exhibit A, and thus may have been missed by the Examiner.

Based on these remarks and the attached 131 declaration, Applicants respectfully request that the rejection under 35 U.S.C. § 102(e) over the '047 patent be reconsidered and withdrawn.

***Rejections under 35 U.S.C. ' 103***

(a) The Examiner has maintained the rejection of pending claims 492, 493, 495-503, 506-521, 523-531, 535-539, 541-549, 608, 611-619, and 622 under 35 U.S.C. § 103(a) as allegedly being rendered obvious by the '047 patent. In making this rejection, the Examiner specifically cites the March 12, 1997 priority document, relied upon under 35 U.S.C. § 120 in the '047 patent, for disclosure of a DNA fragment encoding a polypeptide fragment which, according to the Examiner, is identical to amino acids 256-306 of SEQ ID NO:2 of the present application. The Examiner alleges that as later shown in the '047 patent, the fragment disclosed in the March 12, 1997 priority document inherently functions within a mature DR5 to induce apoptosis. *See* Paper No. 34 at pages 6-8.

Applicants respectfully traverse. As stated above, Applicants were in possession of the subject matter of the pending claims, in the United States, before March 12, 1997. *See* attached 131 declaration. Accordingly, the disclosure of the March 12, 1997 priority document is unavailable as a reference.

(b) The Examiner has maintained the rejection of claims 287-299, 319, 326-339, 351, 353-373, 389, 391-415, 431, 434-442, 446-458, 476, 478-491, 553-565, and 567-594 under 35 U.S.C. § 103(a) as allegedly being rendered obvious by the '047 patent. In making this rejection, the Examiner cites U.S. Patent Appl. No. 08/799,861, filed on February 13, 1997 (the "February 13, 1997 priority document"), relied upon under 35 U.S.C. § 120 in the

'047 patent, for disclosure of an isolated mature TRAIL-R protein, in addition to the March 12, 1997 priority document described above. The Examiner alleges that, based on the disclosures of the February 13, 1997 and March 12, 1997 priority documents, the above listed claims would be rendered obvious. *See* Paper No. 34 at pages 8-10.

Applicants respectfully traverse. As stated above, Applicants were in possession of the subject matter of the pending claims, in the United States, before March 12, 1997. *See* attached 131 declaration. Accordingly, the disclosure of the March 12, 1997 priority document is unavailable as a reference.

Furthermore, for the reasons stated in the Amendment and Reply dated June 4, 2002, Applicants maintain that the February 13, 1997 priority document relied upon by the Examiner is insufficient to sustain a *prima facie* case of obviousness on its own.

Based on these remarks and the attached Declaration, Applicants respectfully request that all rejections under 35 U.S.C. § 103(a), as applied to the pending claims, be withdrawn.

### ***Objections to the claims***

The Examiner has objected to claims 320-325, 352, 390, 432, 477, and 566 for being dependent on a rejected base claim. Based on the reasons set forth above, Applicants believe that all pending claims are allowable, thus removing the Examiner's objection.

### ***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be

withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Elizabeth J. Haanes", with a long horizontal flourish extending to the right.

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